contends that the specification fails to provide any demonstrable evidence that applicants had generated the claimed antibodies and immune complexes. The Examiner further contends that there is no indication that applicants contemplated making and/or using the claimed antibodies and immune complexes. The Examiner states that applicants may obviate the rejection by providing scientific evidence that the claimed antibodies and immune complexes were actually generated. Applicants traverse the rejection.

Applicants respectfully submit that the Examiner is not applying the appropriate standard for determining compliance with the written description requirement. Applicants respectfully submit that the standard used by the Examiner does not take into account what is conveyed by the specification to the skilled artisan, and is, therefore, not the appropriate standard for determining whether the specification fulfills the written description requirement of 35 U.S.C. § 112.

As described in M.P.E.P. § 2163.02, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter. Ralston Purina Co. V. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985). When the original specification accomplishes that conveyance, regardless of how it accomplishes it, the essential goal of the description requirement is realized. In re Wright, 866 F.2d 422, 424, 9 U.S.P.Q. 2d 1649, 1651 (Fed. Cir. 1989). In deciding the issue, the specification as a whole

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must be considered. 866 F.2d at 425, 9 U.S.P.Q. 2d at 1651. In addition, the subject matter of a claim does not need to be described literally in order for the disclosure to satisfy the description requirement. Id. Thus, one must peruse the full scope of the disclosure, the working examples, the stated objectives, and all of the embodiments in order to determine whether the written description conveys the invention to one skilled in the art.

Solely to expedite prosecution of the pending claims, applicants have canceled claims 15, 16, and 18-20, amended claims 29 and 30, and added new claims 37-44. Applicants submit that these claims are fully supported by the specification.

The specification teaches that the invention relates to biological reagents that can be formed using HIV-1 extracts containing the p25 protein or using purified p25 protein, particularly for the **production of antibodies in animals or monoclonal antibodies**. (Specification at 30-31, bridging paragraph.)

Furthermore, the specification teaches that the invention concerns **all extracts** of the virus, including crude lysates, more purified lysates, and purified proteins. (Id. at 14, paragraph 3.) The specification teaches detailed purification procedures for the generation of crude viral extracts, and detailed procedures for the generation of purified viral antigens, which include p12, p18, p25, p15, p36, p42, and p80. (Id. at 11-13 and 21-23.) The skilled artisan is taught that the invention relates to the use of these extracts (both crude lysates and purified proteins) to generate antibodies in animals, as well as to generate monoclonal antibodies. (Id. at 30-31, bridging

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paragraph.) New claims 37-43 recite antibodies generated using these antigens. Therefore, applicants submit that new claims 37-43 are fully supported by the specification.

Claims 29-31 are drawn to isolated immunological complexes. The specification describes the purification of immunocomplexes formed by interaction of patient sera with viral extracts. (Id. at 12, paragraph 2.) Applicants further submit that immunoprecipitation is an art recognized technique for purifying immune complexes. As detailed above, the specification teaches purified p12, p18, p25, p15, p36, p42, and p80 HIV-1 antigens. The skilled artisan is taught that immune complexes between these antigens and anti-HIV-1 antibodies can be purified by immunoprecipitation. (Id.) Furthermore, the specification teaches that the invention encompasses any type of immunological assay, and recites immunofluorescence, immunoenzymatic assays, and radioimmunoprecipitation assays as particularly suitable. (Id. at 14, paragraph 2.) As an additional example, the specification teaches detailed procedures for purifying immunocomplexes between HIV-1 extracts and anti-HIV-1 antibodies using an ELISA. (Id. at 17-26.) The specification also teaches labeled virus extracts including fluorescent, enzymatic, and radioactive labeling. (Id. at 17, paragraph 5.) As an example, the specification teaches using an enzymatically labeled antibody. (Id. at 17-18.) Therefore, applicants submit that new claims 29-31 are fully supported by the specification.

Claim 44 is drawn to antibodies purified from human sera using HIV-1 extracts. The specification teaches detailed procedures for the preparation of HIV-1 extracts and their use in an

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ELISA assay to purify antibodies, which bind to antigens in the HIV-1 extracts, from human sera. (Id. at 17-26.) Furthermore, the specification teaches that the invention concerns all extracts of the virus, including crude lysates, more purified lysates, and purified proteins. (Id. at 14, paragraph 3.) The specification teaches detailed purification procedures for the generation of crude viral extracts and detailed procedures for the generation of purified viral antigens, which include p12, p18, p25, p15, p36, p42, and p80. (Id. at 11-13 and 21-23.) Therefore, the skilled artisan recognizes that antibodies specific for each these antigens could be purified by conventional immunological techniques, for example by ELISA. Furthermore, the specification teaches that the invention encompasses any type of immunological assay, and recites immunofluorescence, immunoenzymatic assays, and radioimmunoprecipitation assays as particularly suitable. (Id. at 14, paragraph 2.) Accordingly, applicants submit that claim 39 is fully supported by the specification.

The specification teaches HIV-1 extracts, both crude and purified. The specification teaches that purified HIV-1 extracts contain HIV-1 p12, p18, p25, p15, p36, p42, and p80. The specification teaches that immunological complexes between these antigens and anti-HIV-1 antibodies can be purified. The specification teaches that antibodies against viral antigens can be purified. The specification teaches that HIV-1 extracts, both crude and purified, can be used to generate antibodies in animals, including monoclonal antibodies. Therefore, applicants submit that the claimed invention is reasonably conveyed to the skilled artisan by the specification.

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Accordingly, applicants submit that, under the appropriate standard, applicants have fulfilled the written description requirement under 35 U.S.C. § 112, and respectfully request withdrawal of the rejection.

Claims 18-20 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 10-13, and 18-22 of U.S. Patent No. 5,135,864. The Examiner asserts that it would have been *prima facie* obvious to generate antibodies against the p15, p25, p36, p42, and p80 antigens disclosed in the '864 patent. In addition, claims 15, 16, 18, and 19 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, and 9-11 of U.S. Patent No. 5,217,861. The Examiner asserts that it would have been *prima facie* obvious to generate antibodies against the p12, p18, and p25 antigens disclosed in the '861 patent.

Applicants traverse the rejection. As outlined in M.P.E.P. § 804, a obviousness-type double patenting rejection is primarily intended to prevent the prolongation of the patent term by prohibiting claims in a second patent that are not patentably distinct from claims in a first patent. Applicants submit that the antibodies and immune complexes of the claims in the instant application are patentably distinct from the claims in the '864 and '861 patents. As indicated by the Examiner, the claims in the '864 and '861 patents recite antigens, proteins, and extracts. It is art recognized that antibodies and proteins are distinct subject matter. Therefore, applicants

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submit that the claims in the instant applicantion and the claims in the '864 and '861 patents are patentably distinct. Accordingly, applicants respectfully request withdrawal of the rejection.

In view of the foregoing remarks, applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully Submitted,

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Dated: June 3, 1998

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